

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

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| J.B.D.L. CORPORATION, d/b/a |) | |
| BECKETT APOTHECARY, et al., |) | |
| |) | Civil Action No. 1:01-cv-704 |
| Plaintiffs, |) | |
| |) | Judge Sandra S. Beckwith |
| v. |) | Magistrate Judge Timothy S. Hogan |
| |) | |
| WYETH-AYERST LABS., INC., et al., |) | |
| |) | |
| Defendants. |) | |
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| CVS MERIDIAN, INC. and RITE AID CORP., |) | |
| |) | |
| Plaintiffs, |) | Civil Action No. 1:03-cv-781 |
| |) | |
| v. |) | Judge Sandra S. Beckwith |
| |) | Magistrate Judge Timothy S. Hogan |
| WYETH, |) | |
| |) | |
| Defendant. |) | |
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**DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS
FROM INTRODUCING CERTAIN EVIDENCE
BASED ON THE TESTIMONY OR ANALYSIS OF PAUL SIMON**

Defendants Wyeth Pharmaceuticals (formerly known as Wyeth-Ayerst Laboratories, Inc.) and Wyeth (formerly known as American Home Products Corporation) (collectively "Wyeth") through its attorneys, respectfully move this Court to prohibit Plaintiffs J.B.D.L. Corporation, *et al.*, and CVS Meridian, Inc. and Rite Aid Corporation (collectively "Plaintiffs") from introducing certain evidence based on the testimony or analysis of Paul Simon. In support of this motion, Wyeth relies on the attached memorandum of law.

Dated: May 13, 2005

Respectfully submitted,

s/Grant S. Cowan

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**MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION
TO EXCLUDE PLAINTIFFS FROM INTRODUCING CERTAIN EVIDENCE
BASED ON THE TESTIMONY OR ANALYSIS OF PAUL SIMON**

Defendants Wyeth Pharmaceuticals (formerly known as Wyeth-Ayerst Laboratories, Inc.) and Wyeth (formerly known as American Home Products Corporation) (collectively "Wyeth") move this Court for an Order prohibiting Plaintiffs J.B.D.L. Corporation, *et al.*, and CVS Meridian, Inc. and Rite Aid Corporation (collectively "Plaintiffs") from introducing certain evidence based on the testimony or analysis of Plaintiffs' expert Paul Simon. In support of this motion, Wyeth states as follows:

I. INTRODUCTION AND BACKGROUND

Wyeth manufactures and markets Premarin, an estrogen therapy prescription pharmaceutical product commonly prescribed to relieve symptoms associated with menopause. Plaintiffs allege that Wyeth violated provisions of the Sherman Act by entering into anticompetitive rebate contracts with managed care organizations (“MCOs”) and pharmacy benefit managers (“PBMs”). Plaintiffs allege that Cenestin, an estrogen therapy pharmaceutical product, was unable to compete effectively because of Wyeth’s contracts and assert antitrust claims of monopolization and exclusive dealing. Wyeth denies Plaintiffs’ allegations that Cenestin was foreclosed from the market for estrogen therapy products and will submit substantial evidence at trial that Cenestin’s limited success was not the result of Wyeth’s rebate agreements but instead was attributable to Cenestin’s weakness as a product, its lack of therapeutic indications, its lack of dosage strengths, its lack of scientific studies supporting the product, its inadequate promotion, its flawed pricing strategy and numerous other problems. Wyeth further asserts that Cenestin was available throughout the market place and that the average consumer during the relevant time period would pay almost the same for Premarin or Cenestin regardless of Wyeth’s contracts or Cenestin’s formulary status. Wyeth also notes that Plaintiffs cannot show that Wyeth’s managed care contracts had an adverse effect on the overall estrogen therapy market, which includes numerous competitive products in addition to Cenestin and Premarin.

Plaintiffs retained Paul Simon, R.Ph., as an expert to submit a rebuttal report in an effort to refute the contentions of Wyeth’s experts and the testimony of numerous fact witnesses. Simon is a licensed pharmacist purporting to be an expert in the field of “pharmaceutical marketing.” Simon has never been certified as an expert by any court.

Despite the central thesis of his report – that Wyeth contracts are unreasonable – Simon has admitted in his deposition that he is not an expert in pharmaceutical contracting, nor in managed care, and has not even reviewed the relevant contracts. Additionally, Simon’s report covers numerous other subjects that go beyond his claimed area of expertise, including, pharmaceutical pricing, the importance of formulary position on physician prescribing behavior and the managed care industry. Further, when his report does address his purported area of expertise, it is sorely lacking in facts, data and reliable principles or methodology. Simon’s report and testimony fall outside the scope of Federal Rules of Evidence 702 and 403, as well as the standards contemplated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Accordingly, this Court should exclude the portions of Simon’s testimony described below.

II. THE LEGAL STANDARD

A. Federal Rule of Evidence 702 and the *Daubert* Test

Before a court may consider the substance of an expert’s proposed testimony, it must address the “[p]reliminary questions concerning the qualifications of a person to be a witness.” Fed. R. Evid. 104(a). Federal Rule of Evidence 702 requires that, to qualify as an expert, a witness must first establish his or her expertise by reference to “knowledge, skill, experience, training or education.” *Pride v. BIC Corp.*, 218 F.3d 566, 577 (6th Cir. 2000); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592, n.10 (1993). The Sixth Circuit has stated that the trial court must examine the expert’s qualifications, not in the abstract, but with regard to “whether those qualifications provide a foundation for a witness to answer a specific question” and “whether the expert’s training and qualifications relate to the subject matter of his proposed testimony.” *Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303 (6th Cir.

1997) (abrogated on other grounds) (citations and quotations omitted). The Sixth Circuit has repeatedly held that an expert may not testify to subjects that are beyond his or her area of expertise. *See, e.g., Smelser*, 105 F.3d at 305 (holding lower court erred in admitting the testimony of expert concerning a seatbelt where testimony went outside expert's field of biomechanics); *Berry v. City of Detroit*, 25 F.3d 1342, 1351-52 (6th Cir. 1994) (finding expert in "police policies and practices" lacked qualifications to testify as to whether disciplinary problems in a police force caused a shooting death); *In re Meridia Prods. Liab.*, 328 F. Supp. 2d 791, 805 (N.D. Ohio 2004) (holding pharmacist may not testify on subjects properly directed to a cardiologist). The proponents of the expert bear the burden of showing that he or she is qualified to render an expert opinion on matters related to the case. *In re Meridia Prods. Liab.*, 328 F. Supp. 2d at 804.

If an expert is properly qualified, his or her testimony must satisfy three prerequisites outlined in Federal Rule of Evidence 702 before being admitted: (1) the testimony must be based upon sufficient facts or data, (2) the testimony must be the product of reliable principles and methods, and (3) the witness must have applied the principles and methods reliably to the facts of this case. In a case following and applying *Daubert*, the Supreme Court held that a court must determine "whether the principles and methodology underlying the testimony itself are valid." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). Under *Daubert*, a court must exclude testimony that does not "rest[] on a reliable foundation and is [not] relevant to the task at hand." *Daubert*, 509 U.S. at 597. "Where [the expert] testimony's factual basis, data, principles, methods, or their application are called sufficiently into question" the trial court should evaluate that testimony before allowing it to be admitted. *Kumho Tire*, 526 U.S. at 149 (citations omitted).

B. Federal Rule of Evidence 403

Additionally, even if proffered expert analysis can withstand *Daubert* scrutiny, it must also meet the requirements of Federal Rule of Evidence 403. Under Rule 403, evidence must be excluded, even if it is relevant, “if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.” Fed. R. Evid. 403. Thus, a court confronted with expert analysis that passes the *Daubert* test must still determine if the proffered evidence survives Rule 403 scrutiny. *See Kurncz v. Honda N. Am., Inc.*, 166 F.R.D. 386, 388 (W.D. Mich. 1996). Evidence may be excluded under Rule 403 if “the expert’s opinion rests on a foundation so unreliable that it should be excluded from consideration.” *Robinson v. Union Carbide Corp.*, 805 F. Supp. 514, 523 (E.D. Tenn. 1991); *see also Wolfel v. Holbrook*, 823 F.2d 970, 973-74 (6th Cir. 1987).

III. SIMON’S OPINIONS SHOULD NOT BE ALLOWED

Simon is not qualified to testify as an expert in several fields in which he purports to offer expert analysis. Additionally, much of Simon’s proffered analysis cannot withstand *Daubert* scrutiny. Even if Simon’s analysis could meet these requirements, it should be barred under Rule 403 because its foundation is too unreliable to be probative. Specifically:

- Simon inappropriately opines on issues concerning managed care contracts, despite expressly admitting he is not qualified to give expert testimony in this field;
- Simon inappropriately opines on issues concerning pharmaceutical pricing despite expressly admitting he is not qualified to give expert testimony in this field; additionally, Simon’s analysis is not based on any quantitative analysis of Cenestin’s pricing;
- Simon inappropriately opines on the importance of formulary position on physician prescribing behavior; Simon’s limited experience with physicians is not a sufficient basis to support his analysis;

- Simon's opinions comparing the pharmacologic aspects of Cenestin and Premarin are contrary to FDA conclusions and are not based on any studies or data;
- Simon inappropriately opines on issues concerning the managed care industry, despite expressly admitting he is not qualified to give expert testimony in this field;
- Simon's opinion that a lack of demand for Cenestin did not impact its sales or formulary position was formed without consideration of relevant data.

Each of these reasons for excluding Simon's report and testimony is explained in greater detail below.

A. Simon's Testimony Concerning Wyeth's Contracts Should Be Excluded

Simon is a licensed pharmacist. By his own admission, he is not an expert in the field of managed care contracts. However, the sixth heading of his report and subsequent discussion provide: "Wyeth's Rebate Contracts and Their Enforcement Were Not Standard in the Industry." (Ex. 1, Report at 20). Despite having a section of his report to that effect, Simon admitted his lack of expertise to render such an opinion:

Q. And in fairness, do you really think you have an understanding of the ins-and-outs of these contracts, such that you can give expert testimony, under oath, as to what is the "norm" for rebate contracts from 1991 to the present?

A. *I would not hold myself out to that. You're correct.*

(Ex. 2, Simon 10/11/02 Dep. at 250:1-7 (emphasis added)).

Q. And, looking at page 250 of your deposition, right at line one, where it says: "In fairness, do you really think that you have an understanding of the ins and outs of these contracts, such that you can give expert testimony under oath as to what the 'norm'," in quotes, "is for rebate contracts from 1991 to the present."

And, then you answer by stating: "I would not hold myself out to that, you are correct." Is that still true, sir?

A. I do not hold myself out as an expert in managed care.

(Ex. 3, Simon 10/14/04 Dep. at 64:2-15).

Simon's lack of expertise is compounded by his lack of analysis of the facts and data in this case. For example, he argues that it is "not standard industry practice to bundle branded products" in contracts. (Ex. 1, Report at 20). Yet, he admits not only that he is not an expert in this area, but also that he did not consider the relevant contracts:

Q. . . . [I]n terms of looking at the contracts that have been produced in the litigation, counsel didn't provide those to you then for you to review and –

A. I didn't ask for them. They didn't provide them.

Q. Alright. And so if you wanted to determine how many of these contracts were bundled, you could have looked at those contracts, but you didn't, correct?

A. Correct.

(Ex. 3, Simon 10/14/04 Dep. at 158:22-159:10). Much the same, Simon states in his report that Wyeth's contracting was not standard because Wyeth refused to renegotiate contracts, citing Wyeth's contract with a pharmacy benefit manager, Express Scripts. (Ex. 1, Report at 20). But in his deposition, Simon admits:

Q. Okay. But you haven't done the work to look and see whether or not, in fact, Wyeth was willing to negotiate and allow Cenestin to be placed on the formulary at Express Scripts, correct?

* * *

A. Correct.

(Ex. 3, Simon 10/14/04 Dep. at 138:15-21). In other words, Plaintiffs want to offer expert testimony that Wyeth's contracts were not standard in the industry, but the purported expert not only lacks expertise on that subject, but did not even ask for or review the relevant contracts.

Given Simon's admission that he is not an expert in managed care contracting, and has not even reviewed the contracts in issue, his opinion lacks the necessary foundation for

admissibility under *Daubert* and the Federal Rules of Evidence. Further, Simon's report lacks any citation supporting this opinion as required by the Rules. Finally, Simon's report and testimony are insufficient under a *Daubert* analysis because it does not rest on a reliable foundation.

B. Simon's Testimony Concerning Pharmaceutical Pricing Should Be Excluded

In his report, Simon offers numerous opinions concerning the pricing of Cenestin. For example, on page 4 of his report he explains, "I disagree with Dr. Kolassa regarding Cenestin's initial pricing. In my opinion, Duramed followed a prudent pricing strategy." (Ex. 1, Report at 4). The crux of these portions of his report argue that even though Cenestin was a new product, with limited FDA approved indications, a limited sales force and no scientific literature supporting it, that it was "prudent" to price Cenestin at parity to Premarin. (Ex. 1, Report at 4, 14-19). Simon also devotes an entire section of his report to pricing and co-payments, under the heading "Retail prices are not insignificant compared to MCO co-payments." (Ex. 1, Report at 11-13).

Despite having these sections in his report, Simon conceded in his deposition: "*I don't hold myself out as a pricing expert.*" (Ex. 3, Simon 10/14/04 Dep. at 86:17-21). Simon further admitted that his prior experience in the pharmaceutical industry did not concern pricing. (Ex. 3, Simon 10/14/04 Dep. at 87:19-88:20). Upon additional inquiry, Simon revealed that although "there is research that can be done to arrive at an appropriate price," he has not performed *any quantitative analysis* concerning Cenestin's pricing:

Q. Have you done that type of a quantitative analysis in this case to determine whether or not Cenestin had an appropriate price?

A. Have I physically done –

Q. Yes, sir.

A. No, sir.

(Ex. 3, Simon 10/14/04 Dep. at 86:19-87:4).

Consistent with his lack of experience and analysis, Simon conceded that he has seen no research or studies indicating whether price differentials between the two products of \$3.43 to \$13.40 – the amount shown in his chart on Page 13 – would or would not influence demand. (Ex. 3, Simon 10/14/04 Dep. at 255:6-257:7).

Given Simon's admission that he is not an expert on pricing, Simon is not qualified to provide testimony on this subject under Federal Rules of Evidence 104(a) and 702. Additionally, given that he has not performed any quantitative analysis concerning Cenestin's pricing, this analysis lacks the grounding in sufficient facts and data required under *Daubert* and Federal Rule of Evidence 702.

C. Simon's Testimony Concerning the Effect of Formulary Position on Physician Prescribing Behavior Should Be Excluded

Simon provides extensive opinion concerning the effect of formulary position on physician prescribing behavior. However, Simon has extremely limited experience working with physicians and failed to consider relevant data in forming his conclusions. Simon's experience with interviewing physicians upon which he relies (1) occurred in 1983 – well before the managed care industry was fully developed particularly as it relates to pharmaceuticals and (2) consisted of interviews with between 12-24 doctors total – having nothing to do with this case or the prescribing habits of doctors writing prescriptions for Premarin or Cenestin. (Ex. 3, Simon 10/14/04 Dep. at 192:1-194:7, 181:3-181:9). Simon lacks the expertise to opine on the effect of formulary position on physician prescribing behavior.

Yet in his report, Simon opines extensively on physician behavior concerning formularies issued by their patients' managed care organizations in the sections of his report bearing the headings, "Restriction in 25%-40% of the market is sufficient to seriously affect Cenestin's sales" and "Spillover exists and pharmaceutical manufacturers take advantage of it." (Ex. 1, Report at 9-11). For example, Simon asserts, "[e]ven if Cenestin is explicitly excluded from 25%-40% of managed care lives, this figure is still sufficiently restrictive to result in decreased Cenestin prescribing by physicians." (Ex. 1, Report at 9). Later he opines, "[m]y own experience with physician interviews is that they tend to use the products that generate the least calls from pharmacists and patients" (Ex. 1, Report at 10) and "[d]octors do not use different products for different classes of patients" (Ex. 1, Report at 11).

Much the same, Simon argues that Cenestin's mediocre performance in the cash and Medicaid market (which lack formularies) proves nothing about the impact (or lack thereof) of Wyeth's contracts with MCOs on Cenestin. (Ex. 1, Report at 9-11). But when questioned in his deposition whether physicians are aware that their patients are either covered by insurance or are paying cash, Simon conceded he had not considered any data on the subject (although it exists). (Ex. 3, Simon 10/14/04 Dep. at 192:1-18). This gap in his analysis significantly undermines his conclusions concerning "spillover" because his premise is that physicians will not prescribe a drug for *any* patients when some insurers do not include the product on formulary. If physicians are aware of a patient's method of payment on this basic level – which is very likely – then Simon's "spillover" theory simply fails.

Accordingly, it is clear that Simon is not qualified to issue expert opinion concerning physicians prescribing habits as required by Federal Rules of Evidence 104(a) and 702. Further, his testimony on this subject should be excluded under *Daubert* and Federal Rule

of Evidence 403 because the foundation on which it is based does not take significant facts into consideration.

D. Simon's Opinion Comparing the Pharmacologic Aspects of Cenestin and Premarin is Inadmissible

On pages 3 and 4 of his report, Simon opines that "Cenestin compares favorably to Premarin." (Ex. 1, Report at 3-4). Much the same, Simon opines "pharmacists and physicians expect Cenestin and Premarin to work in a similar if not identical set of indications and uses." (Ex. 1, Report at 4). However, Simon's opinion suffers from the same infirmities discussed above – a lack of expertise and analysis. For example, after providing his opinion that, contrary to Cenestin's FDA approval and label, physicians would nevertheless assume that Cenestin has the same indications as Premarin, Simon admitted the following:

Q. And have you done any study of pharmacists or physicians to confirm that opinion?

A. No.

(Ex. 3, Simon 10/14/04 Dep. at 99:14-17). Similarly, although Simon has the opinion that Cenestin's pharmacokinetic profile compares favorably to Premarin (Ex. 1, Report at 3), he admits that there is no data or study indicating that there is any clinical significance to this claim:

Q. The notion that Duramed's Cenestin product has a smooth, steady release, there is no study that has been done that indicates that this has any clinical significance in a patient, correct? Or you're not aware of any, are you?

A. I am not.

(Ex. 3, Simon 10/14/04 Dep. at 69:12-19).¹ For these reasons, Simon's opinions on Cenestin's favorable clinical profile and other such unsupported claims should be excluded as lacking sufficient support and data under *Daubert*.

¹ The only "scientific" data that Simon cites supporting the notion that Premarin and Cenestin have the same indications are from a website from a managed care organization (Medco) and is contrary to the FDA guidance on

E. Simon Is Not An Expert In Managed Care

Despite offering an expert opinion on managed care and the availability of Cenestin within managed care, Simon conceded in his deposition: *“I do not hold myself out as an expert in managed care.”* (Ex. 3, Simon 10/14/04 Dep. at 64:14-15). Not only does Simon not consider himself an expert in managed care but he admitted that he had limited experience with managed care. (Ex. 3, Simon 10/14/04 Dep. at 50:8-56:20). With little experience, he then candidly admitted that he has read none of the depositions of the Duramed witnesses and Duramed managed care personnel concerning the managed care issues that are the subject of his report. (Ex. 3, Simon 10/14/04 Dep. at 44:13-46:12).

Despite fully disclaiming expertise in the managed care industry and after failing to make a review of the relevant facts and data, Simon’s rebuttal report is replete with opinions concerning managed care. For example, Simon contests numerous issues in Dr. Kolassa’s report for Wyeth concerning the use of formularies in the managed care industry, asserting, “Cenestin had sufficient indications, dosage strengths and characteristics that gave it value in the market at the time of typical formulary review.” (Ex. 1, Report at 2-3). He also presents the conclusion: “[T]he fact that a formulary is designated as ‘open’ does not equate to equal access or reimbursement.” (Ex. 1, Report at 3). Similarly, on page 7 of his report Simon again engages in a discussion concerning MCO and PBM behavior, and how they determine their formularies. (Ex. 1, Report at 7). Simon also argues that Cenestin “did not have equal access to 60-75% of managed care lives.” (Ex. 1, Report at 7-14).

Cenestin. (Ex. 1, Report at 5). This is the precise type of hearsay that should be excluded. Instead of being the type of reliable information upon which an expert’s opinion would normally be based, Simon relies on data that Wyeth and *Plaintiffs* know is wrong. Indeed, Plaintiffs know full well that the FDA has concluded that Premarin and Cenestin do not have the same indications *and* that Medco’s P&T committee understood the difference between the products and that Cenestin did not have the same indications as Premarin when Medco decided not to put Cenestin on Medco’s formulary. (See Ex. 4, Nardin Deposition Exhibit 33 at MM 00333; Ex. 5, Nardin Deposition Exhibit 35 at MM 00490).

Compounding the admission of no expertise, lack of experience and lack of analysis, Simon's conclusions are so lacking in a review of the actual data that they fail the *Daubert* test. While he opines that Cenestin was significantly disadvantaged by managed care, he was unfamiliar with the evidence in this case that Cenestin was typically reimbursed just like Premarin by managed care organizations regardless of formulary position (even ignoring the cash and Medicaid markets where it was clearly on equal footing). (Ex. 3, Simon 10/14/04 Dep. at 159:19-163:5). Simon similarly ignored all evidence from Duramed indicating that when a Cenestin prescription was taken to a pharmacy it would generally be reimbursed at the same co-pay as Premarin – although such evidence would likely be relevant to his opinion. (Ex. 3, Simon 10/14/04 Dep. at 175:4-15).²

For example, Simon offers the opinion that “restrictions in 25-40% of the market is sufficient to seriously affect Cenestin's sales.” (Ex. 1, Report at 9). His report then covers various techniques and restrictions used to influence prescription behavior/formulary compliance. (Ex. 1, Report at 9-10). But Simon was forced to concede that he has not analyzed the data or evidence in this case to determine whether in fact (contrary to the evidence) such restrictions were used in this low-cost product category. Instead, Simon testifies as follows:

Q. Here is my question for you, sir, are you aware as to whether or not that has happened in this case?

A. Specifically to Cenestin, no.

Q. All right. In fact, are you aware of whether or not prior authorizations are used in any significant extent by managed care as it relates to Cenestin and this entire low cost category?

² Instead, Simon's report relies upon an industry report sponsored by another pharmaceutical company, Novartis, which is not specific to Premarin, Cenestin, or this product category. In other words, while he is not a managed care expert, he has chosen another source that relates to pharmaceutical products generally and not how Cenestin was handled specifically. (Ex. 3, Simon 10/14/04 Dep. at 168:18-22). Without expertise in managed care, Simon then misapplies the data and has not done any analysis as to why the factual evidence from this market is or is not correct.

A. I do not know if they have implemented prior authorization to Cenestin, no.

Q. And do you know whether or not [NDC] blocks are used in connection with Cenestin?

A. I do not know that.

(Ex. 3, Simon 10/14/04 Dep. at 180:11-181:2).

Given Simon's admission that he is not an expert on the managed care industry, Simon is not qualified to provide testimony on this subject under Federal Rules of Evidence 104(a) and 702. Simon's analysis also lacks the grounding in sufficient facts and data required under *Daubert* and Federal Rule of Evidence 702.

F. Simon's Opinion That a Lack of Demand For Cenestin Did Not Impact Its Sales or Formulary Position Should be Excluded

Even though Simon admitted he is not an expert on managed care, on pages 6 and 7 and throughout his report, Simon offers the opinion that Cenestin's clinical infirmities and a lack of physician/consumer demand had nothing to do with Cenestin's performance and that the decision to not put Cenestin on a managed care formulary "was a decision to be made by others based on financial considerations." (Ex. 1, Report at 3-7). Like the rest of his report, however, this opinion is completely lacking in data, evidence or methodology for his conclusions. Further, it is not only insufficient on its face, but inherently implausible. The *only* citation purportedly supporting his thesis is to the deposition of an executive from Express Scripts, Jim Hill, who according to Simon, supports his opinion that "demand from physicians and consumers" are irrelevant to formulary decision with respect to "competitors like Cenestin and Premarin with similar uses and conjugated estrogen names." (Ex. 1, Report at 7). But in fact, Simon was

unaware of any P&T committee that actually believed Cenestin and Premarin had similar clinical profiles:

Q. Okay, so you agree with the notion that when you do have similar clinical profiles, that you can consider financial considerations for product and for [formulary] inclusion?

A. I agree at least that. Yes.

Q. *And do you know of any P&T committees, any PBMs or HMOs that thought that Cenestin had a similar clinical profile to Premarin?*

A. *I have no idea whether they thought it was a similar clinical profile*

(Ex. 3, Simon 10/14/04 Dep. at 128:17-129:8 (emphasis added)). Insofar as Simon cited to Jim Hill from Express Script, he then admitted as follows:

Q. . . . [I]s it not your testimony, is it, that Express Script's P&T committee concluded that Cenestin had a similar clinical profile to Premarin, is it?

A. No.

Q. Okay.

A. *I have not attended any of these P&T meetings. I have no idea.*

(Ex. 3, Simon 10/14/04 Dep. at 130:4-11 (emphasis added)). Simon was then shown Jim Hill's deposition (which Simon miscited in his report) and Hill's explanation that in fact Express Script's P&T committee specifically characterized Premarin as the "clinically superior product." (Ex. 3, Simon 10/14/04 Dep. at 130:18-132:9).

Much the same, while rejecting the notion that physician and consumer demand plays a role in formulary position, Simon did not do any quantitative analysis of the number of Cenestin prescriptions in relation to the number of sales calls. (Ex. 3, Simon 10/14/04 Dep. at

226:22-227:5). Similarly, Simon ignored Congressional studies cited by other experts (in fact co-authored by one of Plaintiff's other experts) indicating that new pharmaceutical product promotion costs typically equal 100% of the first year's sales:

Q. Let me ask you this, because I asked you this in your last deposition and you asked for a copy of that report, and you got your deposition, you got the exhibits, and that was two years ago.

Two years ago, Sir, I asked you the question can you think of any brand pharmaceutical product that got \$100 or \$150 million in sales without spending \$100 or \$150 million in marketing and you said, off the top of my head, your answer was I cannot.

A. No.

Q. Sitting here today, two years later having had this document, can you name any branded pharmaceutical that got \$100 or \$150 million in sales without spending \$100 or \$150 million in advertising expenses.

A. I have not researched it.

Q. Okay. And you have been looked at the marketing issue either?

A. No.

(Ex. 3, Simon 10/14/04 Dep. at 215:2-22).

In sum, Simon's opinion that lack of demand for Cenestin did not play a role in its performance or in the formulary decisions making of managed care organizations is lacking data and evidence to such an extent that it is simply inadmissible under *Daubert* and the Federal Rules of Evidence.

IV. CONCLUSION

This Court should issue an Order excluding the portions of Simon's expert report and testimony regarding managed care contracting, pharmaceutical pricing, the importance of formulary position on physician prescribing behavior, the managed care industry and the effect of the lack of demand of Cenestin on its sales and formulary position. Simon admits he is not qualified to provide expert testimony on a number of these issues. In addition, this testimony fails to take into account critical facts and data necessary to render an informed opinion. Simon's report and testimony fail to meet the standards required by Federal Rules of Evidence 702 and 403, and *Daubert*. Accordingly, these portions of Simon's report and testimony should be excluded.

Dated: May 13, 2005

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned, an attorney, hereby certifies that a copy of the foregoing Motion to Exclude Plaintiffs from Introducing Certain Evidence Based On the Testimony or Analysis of Paul Simon and Memorandum in Support thereof has been served electronically on all counsel of record with CM/ECF Registration on this 13th day of May, 2005, and by regular U.S. mail, postage prepaid upon the following:

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